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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/806,540	03/23/2004	Jorge L. Orbay	HAN-031	2499
7590 02/06/2006			EXAMINER	
Gordon & Jacobson, P.C. 65 Woods End Road Stamford, CT 06905			SHAFFER, RICHARD R	
			ART UNIT	PAPER NUMBER
			3733	

DATE MAILED: 02/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/806,540	Applicant(s) ORBAY ET AL.	
	Examiner Richard R. Shaffer	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 25 and 26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 March 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. <u>1/30/06</u> |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/12/04, 10/13/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

During a telephone conversation with David Jacobson on January 30th, 2006 a provisional election was made without traverse to prosecute the invention of a cap and nail, claims 1-24. Affirmation of this election must be made by applicant in replying to this Office action. Claims 25 and 26 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Drawings

The drawings are objected to because of minor informalities, see attached Notice of Draftsperson's Patent Drawing Review for specific errors. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief

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description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 15 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification states (Page 6, Paragraph 1) that the third diameter is slightly smaller than the second diameter solely because the nail is located within the structure deforming it. This is not the normal structure of the device and thus cannot be claimed as such.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4-7, 11, 12, 15 and 19-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Finlayson (US Patent 5,885,227).

Finlayson discloses a resilient radiopaque plastic (Column 2, Lines 40-42) cap (20) comprising a cylindrical lead-in portion (left most portion of 20) having a first diameter; a cylindrical engagement portion having a two inner surfaces defining second (in-between portions 12c and 12d) and third (about portion 12d) diameters; a protuberance found at the junction between the two engagement portion projecting radially inward; a closed end (22) opposite the lead-in portion; the length of the cap at least three times the inner diameter (see Table); the cap in combination with a metal nail (12d), the end of the nail being non-passivated cutting end (could cut tissue).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8-10 and 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Finlayson.

Finlayson discloses the claimed invention except for the lead-in portion having an inner diameter range of 0.08 - 0.092 inch, an engagement portion having an inner diameter range of 0.070 - 0.084 inch, and a cap length of 0.285 - 0.310 inch. It would

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have been obvious to one having ordinary skill in the art at the time the invention was made to determine the claimed structural limitations for use in a separate body area (not the blood vessels), since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Finlayson in view of Erskine (US Patent 5,797,880).

Finlayson discloses all of the claimed limitations except is silent on whether or not the radiopaque plastic is polyurethane. Erskine teaches a catheter (Column 5, Lines 1-3) preferably formed from polyurethane, which softens from exposure to physiological conditions present in a patient's body. This allows for easier insertion through the body minimizing damage to the tissue. Applicant has expressed the importance of shielding the body from insertion in the current application. Thus it would have been obvious to one having ordinary skill in the art at the time the invention was made to manufacture the radiopaque insertion cap of Finlayson from polyurethane in order to minimize tissue damage during insertion.

Claims 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Finlayson in view of Jain (US Patent 5,250,072).

Finlayson discloses all of the claimed limitations except for the inner protuberance being a ring with a convex outer surface. Jain teaches (Column 1, Lines 20-57) that current covers when exposed to heat expand and come loose and that round annular ridges increase the grip even under these conditions. Thus it would have

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been obvious to one having ordinary skill in the art at the time the invention was made to provide internal annular ridges to provide a secondary means of ensuring that the plastic tip of Finlayson does not become detached from the guidewire/nail.

Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard R. Shaffer whose telephone number is 571-272-8683. The examiner can normally be reached on Monday-Friday during (7am-5pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Richard Shaffer

Richard Shaffer
February 1st, 2006


EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER